

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

Rec'd PCTO 24 MAY 2005

PCT

## NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

To:	<b>RECEIVED</b> <b>27 JAN 2005</b> <b>IPR</b>
<b>FLECHSLER, Insa AMERSHAM HEALTH AS Nycoveien 1-2 P.O.Box 4220 Nydalen 0401 OSLO NORVEGE</b>	

Date of mailing  
(day/month/year) 24.01.2005

<b>Applicant's or agent's file reference</b> <b>PN0296-PCT</b>	<b>IMPORTANT NOTIFICATION</b>	
<b>International application No.</b> <b>PCT/NO 03/00395</b>	<b>International filing date (day/month/year)</b> <b>27.11.2003</b>	<b>Priority date (day/month/year)</b> <b>27.11.2002</b>
<b>Applicant</b> <b>AMERSHAM HEALTH AS et al.</b>		

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

#### 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

<b>Name and mailing address of the international preliminary examining authority:</b>  <b>European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465</b>	<b>Authorized Officer</b> <b>Vilz, B</b> <b>Tel. +49 89 2399-2292</b>
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## PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT  
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PN0296-PCT	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/NO 03/00395	International filing date (day/month/year) 27.11.2003	Priority date (day/month/year) 27.11.2002
International Patent Classification (IPC) or both national classification and IPC G01R33/28		
Applicant AMERSHAM HEALTH AS et al.		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 13 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 3 sheets.</p>
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li>I <input checked="" type="checkbox"/> Basis of the opinion</li> <li>II <input type="checkbox"/> Priority</li> <li>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li>IV <input checked="" type="checkbox"/> Lack of unity of invention</li> <li>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li>VI <input type="checkbox"/> Certain documents cited</li> <li>VII <input type="checkbox"/> Certain defects in the international application</li> <li>VIII <input type="checkbox"/> Certain observations on the international application</li> </ul>

Date of submission of the demand 11.06.2004	Date of completion of this report 24.01.2005
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epru d Fax: +49 89 2399 - 4465	Authorized Officer Streif, J Telephone No. +49 89 2399-8194



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/NO 03/00395

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-18 as originally filed

**Claims, Numbers**

1-20 received on 17.12.2004 with letter of 10.12.2004

**Drawings, Sheets**

1/6-6/6 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

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5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).  
*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*
6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
  - the entire international application,
  - claims Nos. 14  
because:
    - the said international application, or the said claims Nos. 14 relate to the following subject matter which does not require an international preliminary examination (specify):  
**see separate sheet**
    - the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
    - the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
    - no international search report has been established for the said claims Nos.
2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:
  - the written form has not been furnished or does not comply with the Standard.
  - the computer readable form has not been furnished or does not comply with the Standard.

**IV. Lack of unity of invention**

1. In response to the invitation to restrict or pay additional fees, the applicant has:
  - restricted the claims.
  - paid additional fees.
  - paid additional fees under protest.
  - neither restricted nor paid additional fees.
2.  This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

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International application No. PCT/NO 03/00395

- complied with.  
 not complied with for the following reasons:

**see separate sheet**

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- all parts.  
 the parts relating to claims Nos. .

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	6, 8-13, 15-17, 19
	No: Claims	1-5, 7, 18, 20
Inventive step (IS)	Yes: Claims	10, 12, 13
	No: Claims	1-9, 11, 15-20
Industrial applicability (IA)	Yes: Claims	1-13, 15-20
	No: Claims	

2. Citations and explanations

**see separate sheet**

**The following documents are referred to in this IPER:**

D1 = WO 02/088766

D2 = WO 98/22022

D3 = WO 99/35508

D4 = US 5,211,166

**1 Re Item III: Non-establishment of opinion**

Claim 14 relates to subject-matter covered by the provisions of Rule 67.1(iv) PCT. This claim defines a method comprising inserting an invasive device into a human or non-human animal body which is considered to represent a method of treatment of the human or animal body by surgery. Moreover, the presence of a surgical step in a multi-step method confers a surgical character on that method.

Even if the definition was limited to a method on a subject in which the invasive device has already been inserted, the method would still imply the surgical step.

According to Rule 67.1(iv) PCT, no opinion is established with respect to the subject-matter of claim 14.

**2 Re Item IV: Lack of unity (Rule 13 PCT)**

The present application contains a number of separate inventions which do not share any common inventive concept, contrary to the requirements of Rule 13 PCT.

The common concept linking together these inventions is the use of a hyperpolarised solid or solution of a high T1 agent for the manufacture of a MR contrast agent comprising nuclei selected from the group consisting of  $^{19}\text{F}$ ,  $^6\text{Li}$ ,  $^{13}\text{C}$ ,  $^{15}\text{N}$ ,  $^{29}\text{Si}$ ,  $^{31}\text{P}$ ,  $^{77}\text{Se}$ ,  $^{111}\text{Cd}$ ,  $^{113}\text{Cd}$ ,  $^{115}\text{Sn}$ ,  $^{119}\text{Sn}$ ,  $^{123}\text{Te}$ ,  $^{125}\text{Te}$ ,  $^{171}\text{Yb}$ ,  $^{195}\text{Pt}$ ,  $^{199}\text{Hg}$ ,  $^{203}\text{TI}$ ,  $^{205}\text{TI}$  and  $^{207}\text{Pb}$  as defined in claim 1. However, this concept is not novel, see item V. Therefore, the defined subject-matter falls apart into a number of separate inventions that do not share any common or corresponding special technical features.

More specifically, claims 1-7 and 15-20 define the use of a hyperpolarised solid or solution of a high T1 agent for the manufacture of a MR contrast agent and an invasive device suitable for use with the contrast agent, respectively. It is considered that these claims do not define any special technical features with respect to D1.

Moreover, claims 8 and 9 define the use of a hyperpolarised solid or solution of a high T1 agent for the manufacture of a MR contrast agent wherein the feature defining that the contrast medium additionally is a therapeutically active medium can be considered as a special technical feature with respect to D1.

Furthermore, claim 10 defines the use of a hyperpolarised solid or solution of a high T1 agent for the manufacture of a MR contrast agent wherein the feature defining that the contrast agent is suitable for a method of examining the fallopian tubes can be considered as a special technical feature with respect to D1.

Moreover, claim 11 defines the use of a hyperpolarised solid or solution of a high T1 agent for the manufacture of a MR contrast agent wherein the feature defining that the contrast agent is suitable for a method of diagnosis and optional surgery on tumours can be considered as a special technical feature with respect to D1.

Furthermore, claim 12 defines the use of a hyperpolarised solid or solution of a high T1 agent for the manufacture of a MR contrast agent wherein the feature defining that the contrast agent is suitable for a method of diagnosis by biopsy can be considered as a special technical feature with respect to D1.

Finally, claim 13 defines the use of a hyperpolarised solid or solution of a high T1 agent for the manufacture of a MR contrast agent wherein the feature defining that the contrast agent is suitable for a method that is an ablation procedure can be considered as a special technical feature with respect to D1.

As a consequence, considering that the different inventions as listed above do not have any of the same or corresponding special technical features in common and that the underlying technical problems do not form a linear linked series of problems in that one solution was specifically adapted to another solution, there is a lack of unity within the meaning of Rule 13 PCT, and the claims actually define 5 groups of

inventions.

**3 Re Item V: Reasoned statement under Rule 43bis.1(a)(i) PCT**

**3.1 Lack of novelty and/or an inventive step (Art. 33(2) and 33(3) PCT)**

**Independent claims 1, 15, 18**

**Claim 1**

- a) The subject-matter of claim 1 would appear to lack novelty with respect to document D1 for the following reasons.

Document D1 discloses (references in parentheses referring to D1):

*Use of a hyperpolarized solid or solution of a high T1 agent comprising nuclei selected from the group consisting of  $^{19}F$ ,  $^6Li$ ,  $^{13}C$ ,  $^{15}N$ ,  $^{29}Si$ ,  $^{31}P$ ,  $^{77}Se$ ,  $^{111}Cd$ ,  $^{113}Cd$ ,  $^{115}Sn$ ,  $^{119}Sn$ ,  $^{123}Te$ ,  $^{125}Te$ ,  $^{171}Yb$ ,  $^{195}Pt$ ,  $^{199}Hg$ ,  $^{203}Tl$ ,  $^{205}Tl$  and  $^{207}Pb$*   
(interpreting the term "solution" as a fluid substance obtained by the action of dissolving, viz. by changing from a solid or gaseous to a liquid state, and taking into account that the perfluorocarbon synthetic blood plasma disclosed in D1 contains  $^{19}F$  nuclei, the perfluorocarbon synthetic blood plasma containing dissolved hyperpolarised  $^{129}Xe$  in solution can be considered to represent a hyperpolarized solution of a high T1 agent comprising  $^{19}F$  nuclei, see page 11, lines 16-26; it is noted that present claim 1 does not define that the nuclei selected from the group form part of the molecular structure of the hyperpolarized high T1 agent itself) and having a T1 value of at least 5 seconds at a field strength of 0.001-5 T and a temperature of 20-40°C (see page 12, lines 25-27 stating that the "decay time" which corresponds to the spin-lattice relaxation time T1 is "of the order of 10 seconds"; moreover, although D1 does neither mention the static magnetic field strength of the MRI system depicted in figure 2, nor the temperature of the solution being injected into the subject (see figure 2 and page 9, line 13 - page 10, line 12), D1 discloses these features implicitly since (i) state-of-the-art MRI scanner suitable for human subjects possess static magnetic field strengths in the range of 1.5 to 3.0 T and (ii) the solution administered to the subject needs to possess a biocompatible temperature whereby temperatures above 40°C would result in potential cell

damage and temperatures below 20° would result in a significant reduction of the subject's heart rate) *for the manufacture of a MR contrast medium* (at least implicitly, D1 discloses the manufacture of a contrast agent by solving the hyperpolarised  $^{129}\text{Xe}$  within the perfluorocarbon synthetic blood plasma, see page 11, lines 23-26) *suitable for use in a method of diagnosis* (see e.g. page 13, lines 17-21) *wherein an invasive device is inserted into a human body* (see page 11, lines 17-20 and figure 1) *and an MR image of at least a part of said body containing said device is generated to visualize said device* (see page 12, lines 12-22).

- b) Moreover, even if the  $^{19}\text{F}$  nuclei would be deleted from the group of nuclei defined in claim 1, amended claim 1 would lack an inventive step with respect to D1 since it would appear that said group defines merely an arbitrary selection of nuclei with non-zero spin which are, therefore, NMR active. However, replacing  $^{129}\text{Xe}$  according to D1 by another type of NMR active nuclei would merely appear as an analogous use that does not involve any inventive skill.
- c) Furthermore, even if the scope of claim 1 was limited, for instance by specifying characteristics of the high T1 agent that are not disclosed in D1 (e.g. T1 value higher than 10 seconds), the subject-matter of amended claim 1 would still appear to lack an inventive step with respect to a combination of documents D1 and D3 since the skilled person, starting from D1 and desiring e.g. to improve the signal-to-noise ratio of the MR visualization of the invasive device disclosed in D1, would employ the contrast agents disclosed in D3 and arrive at the subject-matter of amended claim 1 without the exercise of any inventive skill. In this context, it is noted that D3 discloses contrast agents comprising a hyperpolarized solution of  $^{13}\text{C}$ ,  $^{15}\text{N}$ ,  $^{19}\text{F}$ ,  $^{29}\text{Si}$ ,  $^{31}\text{P}$  or  $^1\text{H}$  (see D3, page 11, 2nd par.).

### Claim 15

- a) The subject-matter of claim 15 would appear to lack an inventive step with respect to a combination of documents D1 and D2 for the following reasons.

The subject-matter of claim 15 differs from that of D1 only in that the elongated

body of the invasive device is made from carbon fibre containing material rather than plastics material or an MRI compatible metal (see D1, figure 1 and page 8, lines 11-21).

The technical effect of the invasive device being made from carbon fibre containing material is that the invasive device is transparent to the RF magnetic field of the MRI system. Accordingly, the invasive device itself can be visualized in MR images.

Therefore, the problem to be solved consisted in visualizing the elongated body of the invasive device disclosed in D1 in MR images.

However, even D1 itself hints at the possibility of imaging the contrast agent within the catheter disclosed therein when using a suitable plastics material (see page 12, lines 18-22).

More specifically, the skilled person would consider document D2 since the same problem is mentioned therein (see D2, page 12, 2nd paragraph). The problem is solved in D2 by forming the invasive device with a carbon-fiber composite material (see page 12, 2nd paragraph).

Therefore, the skilled person would arrive at the subject-matter of claim 15 without the exercise of any inventive skill.

- b) Moreover, the subject-matter of claim 15 would appear to lack an inventive step with respect to a combination of documents D2 and D3 for the following reasons. Claim 15 defines an invasive device **suitable for** use with the contrast medium defined in the preceding claims. However, it would appear that the invasive device disclosed in D2 is suitable for use with the contrast agents disclosed in D3, albeit visualisation is only possible for the time period the signal of the hyperpolarised compound is detectable (e.g. according to D3 during 5-100 s).

It might be tempting to argue that, in the device according to D2, the contrast agent is a permanent part of the device which results in only a limited time

period during which the device can be visualized by use of the hyperpolarized contrast agent. However, D2 does not teach to make the contrast agent a permanent part of the invasive device disclosed therein, but states that "an auxiliary portion of the instrument contains a contrast agent" (page 13, last paragraph) and that "the auxiliary portion is designed to be removed after the instrument has been positioned within the target, and optionally replaced by a substitute portion" (page 14, first paragraph). Therefore, it would not appear that the limited time period wherein the hyperpolarized contrast agent is detectable circumvents the use of the contrast agents disclosed in D3 with the invasive device disclosed in D2.

In contrast, since the benefits of hyperpolarized contrast agents (e.g. very high signal-to-noise ratio in MR images) are well-known in the art, it would appear that the skilled person, starting from D2 and desiring to improve the signal-to-noise ratio of the MR visualization of the invasive device disclosed in D2, would employ the contrast agents disclosed in D3 and arrive at the subject-matter of claim 15 without the exercise of any inventive skill.

### **Claim 18**

The subject-matter of claim 18 would appear to lack novelty with respect to document D1 as well (see figure 1, the bore 4 of the inner tube forms the first lumen, whereas the annular bore 5 between inner and outer tube forms the second lumen; moreover first and second lumens are connected at the opening 6 at the distal end which can be considered as being "in communication").

It should be apparent that the objections given with respect to claim 1 under items b) and c) equally apply to claims 15 and 18, respectively.

### **Dependent claims 2-9, 11, 16, 17, 19, 20**

### **Claims 2-9**

The subject-matter of claims 2-9 is either known from, or rendered obvious by the available prior art (w.r.t. claims 2, 3 see items 3.1 b) and c) above; w.r.t. claim 4 see

D1, page 12, lines 25-27; w.r.t. claim 5 see D1, figure 1; w.r.t. claim 6 it is noted that this feature is obvious from a combination of D1 and D2; w.r.t. claim 7 see D1, page 11, lines 17-26; w.r.t. claims 8, 9 see D3, page 46, 2nd par.).

**Claim 11**

The subject-matter of claim 11 is known from a combination of documents D1 and D3 (see D3, page 16).

**Claims 16, 17**

The additional features of claims 16 and 17 are known from a combination of documents D1 and D2 as well (w.r.t. claim 16 it is noted that in its broadest sense, the word "opaque" is to be interpreted as "being less transparent"; therefore, the additional feature of claim 16 is known from D2 since the carbon-fibre composite material attenuates the RF field to a certain extent; w.r.t. claim 17, see D2, page 12, 2nd paragraph).

**Claim 19**

The additional feature would appear to be one of several straightforward possibilities among the skilled person would select solely in accordance with circumstances, without the exercise of any inventive skill.

**Claim 20**

Taking into account the same interpretation of the word "opaque" as in the objection against claim 16, it would appear that the material used to form the invasive device of D1 attenuates the RF field to a certain extent and, therefore, can be considered to be opaque.

**3.2 Novelty and inventive step of claims 10, 12, 13**

**The objections under items 2 and 3.3 notwithstanding, the subject-matter of claims 10, 12 and 13 would appear to meet the criteria of Art. 33 PCT.** With respect to claim 12 it is noted that, although D4 discloses an invasive device suitable for biopsy, the skilled person would not consider to combine the teachings of D1 and D4.

since the dynamic nuclear polarization performed in D4 is incompatible with the use of the hyperpolarized synthetic blood plasma disclosed in D1.

**3.3 In addition to the objections given above, the following objections under Art. 6 PCT apply.**

**a) Claim 1**

Claim 1 is both unclear and not supported by the description. It is not clear how (and for which purpose) the contrast agent is used. In this context, it is to be noted that claim 1 defines that "**an MR image of at least a part of said body containing said device is generated to visualize said device**". However, claim 1 does not unambiguously define that the "hyperpolarised ... T1 agent" is involved in said visualization.

However, the description uniquely supports that the contrast medium is used for the visualization of the invasive device (see e.g. page 3, last paragraph of the description).

**b) Claim 6**

The scope of the wording "**medium conductive material**" is unclear and should have been defined (e.g. as on page 12, 1st par., last phrase).

**c) Claim 8**

It is not apparent what is to be understood by the term "**a therapeutically active medium**". Therefore, this term should have been defined.

**d) Claim 13**

It is not apparent what is to be understood by the term "**an additional compound effective in this ablation procedure**". Therefore, this term should have been defined.

**e) Claim 18**

The broad wording "**first lumen is in communication with said second lumen**" would appear to cover arrangements not supported by the description (e.g. transfer of heat

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between both lumens, etc). Therefore, the device should have been characterised by defining that first and second lumens are interconnected such that a fluid introduced into the first lumen passes to the second lumen near the distal end of the device.

Claims

1. Use of a hyperpolarised solid or solution of a high T1 agent comprising nuclei selected from the group consisting of  $^{19}\text{F}$ ,  $^6\text{Li}$ ,  $^{13}\text{C}$ ,  $^{15}\text{N}$ ,  $^{29}\text{Si}$ ,  $^{31}\text{P}$ ,  $^{77}\text{Se}$ ,  $^{111}\text{Cd}$ ,  $^{113}\text{Cd}$ ,  $^{115}\text{Sn}$ ,  $^{117}\text{Sn}$ ,  $^{119}\text{Sn}$ ,  $^{123}\text{Te}$ ,  $^{125}\text{Te}$ ,  $^{171}\text{Yb}$ ,  $^{195}\text{Pt}$ ,  $^{199}\text{Hg}$ ,  $^{203}\text{Tl}$ ,  $^{205}\text{Tl}$  and  $^{207}\text{Pb}$  and having a T1 value of at least 5 seconds at a field strength of 0.001-5 T and a temperature of 20-40 °C for the manufacture of a MR contrast medium for use in a method of diagnosis, surgery or therapy wherein an invasive device is inserted into a human or non human animal body and an MR image of at least a part of said body containing said device is generated to visualise said device.
2. Use as claimed in claim 1 wherein said high T1 agent comprises nuclei selected from the group consisting of  $^{13}\text{C}$ ,  $^{15}\text{N}$ ,  $^{19}\text{F}$ ,  $^{29}\text{Si}$  and  $^{31}\text{P}$  nuclei.
3. Use as claimed in claim 1 to 2 wherein said high T1 agent comprises nuclei selected from the group consisting of  $^{13}\text{C}$  and  $^{15}\text{N}$  nuclei.
4. Use as claimed in claims 1 to 3 wherein said high T1 agent has a T1 value of at least 10 seconds or more, preferably 30 seconds or more, more preferably 60 seconds or more and most preferably of more than 100 seconds at a field strength of 0.001-5 T and a temperature of 20-40 °C.
5. Use as claimed in any of claims 1 to 4 wherein the invasive device contains a cavity for holding the contrast medium, the cavity preferably fitted with an outside duct for facilitating circulation and addition of contrast medium.
6. Use as claimed in any of claims 1 to 5 wherein said invasive device is made from a medium conductive material containing carbon fibre.

7. Use as claimed in any of the preceding claims wherein the invasive device is inserted into a tissue and/or vasculature of the human or non-human animal body.
8. Use as claimed in any of the preceding claims wherein the contrast medium additionally is a therapeutically active medium.
9. Use as claimed in claim 8 where the therapeutic active medium is instilled at the region of interest via the invasive device.
10. Use as claimed in any of the preceding claims wherein the method is a method of examining and optionally operating the fallopian tubes.
11. Use as claimed in any of claims 1 to 9 wherein the method is a method for diagnosis and optional surgery on tumours.
12. Use as claimed in any of claims 1 to 9 wherein the method is a method for diagnosis by biopsy, preferably breast or prostate biopsy.
13. Use as claimed in any of claims 1 to 8 wherein the method is an ablation procedure where an additional compound effective in this ablation procedure is introduced through the invasive device.
14. A method of facilitating the visualisation of an invasive device in a human or non-human animal body comprising inserting the invasive device into said body, generating an MR image of at least a part of said body containing said device and introducing a contrast medium into and optionally through said device during the time course of the visualisation procedure, characterised in that the contrast medium comprises a hyperpolarised solid or solution of a high T1 agent comprising nuclei selected from the group consisting of  $^{19}\text{F}$ ,  $^{6}\text{Li}$ ,  $^{13}\text{C}$ ,  $^{15}\text{N}$ ,  $^{29}\text{Si}$ ,  $^{31}\text{P}$ ,  $^{77}\text{Se}$ ,  $^{111}\text{Cd}$ ,  $^{113}\text{Cd}$ ,  $^{115}\text{Sn}$ ,  $^{117}\text{Sn}$ ,  $^{119}\text{Sn}$ ,  $^{123}\text{Te}$ ,  $^{125}\text{Te}$ ,  $^{171}\text{Yb}$ ,  $^{195}\text{Pt}$ ,  $^{199}\text{Hg}$ ,  $^{203}\text{Tl}$ ,  $^{205}\text{Tl}$  and  $^{207}\text{Pb}$  and having a T1 value of at least 5 seconds at a field strength of 0.001-5 T and at a temperature of 20-40 °C.

15. Invasive device comprising a contrast medium comprising a hyperpolarised solid or solution of a high T1 agent comprising nuclei selected from the group consisting of  $^{19}\text{F}$ ,  $^6\text{Li}$ ,  $^{13}\text{C}$ ,  $^{15}\text{N}$ ,  $^{29}\text{Si}$ ,  $^{31}\text{P}$ ,  $^{77}\text{Se}$ ,  $^{111}\text{Cd}$ ,  $^{113}\text{Cd}$ ,  $^{115}\text{Sn}$ ,  $^{117}\text{Sn}$ ,  $^{119}\text{Sn}$ ,  $^{123}\text{Te}$ ,  $^{125}\text{Te}$ ,  $^{171}\text{Yb}$ ,  $^{195}\text{Pt}$ ,  $^{199}\text{Hg}$ ,  $^{203}\text{Tl}$ ,  $^{205}\text{Tl}$  and  $^{207}\text{Pb}$  and having a T1 value of at least 5 seconds at a field strength of 0.001-5 T and a temperature of 20-40 °C, wherein said invasive device comprises a hollow elongated body made from carbon fibre containing material.
16. Invasive device according to claim 15 characterised in that the hollow elongated body is opaque to radio frequency radiation.
17. Invasive device according to claim 15 characterised in that the hollow elongated body is made of carbon-fibre composite material
18. Invasive device comprising a contrast medium comprising a hyperpolarised solid or solution of a high T1 agent comprising nuclei selected from the group consisting of  $^{19}\text{F}$ ,  $^6\text{Li}$ ,  $^{13}\text{C}$ ,  $^{15}\text{N}$ ,  $^{29}\text{Si}$ ,  $^{31}\text{P}$ ,  $^{77}\text{Se}$ ,  $^{111}\text{Cd}$ ,  $^{113}\text{Cd}$ ,  $^{115}\text{Sn}$ ,  $^{117}\text{Sn}$ ,  $^{119}\text{Sn}$ ,  $^{123}\text{Te}$ ,  $^{125}\text{Te}$ ,  $^{171}\text{Yb}$ ,  $^{195}\text{Pt}$ ,  $^{199}\text{Hg}$ ,  $^{203}\text{Tl}$ ,  $^{205}\text{Tl}$  and  $^{207}\text{Pb}$  and having a T1 value of at least 5 seconds at a field strength of 0.001-5 T and a temperature of 20-40 °C, wherein said invasive device comprises a hollow elongated body with a first end and a second end, a first lumen extending from said first end to said second end and a second lumen extending from said first end to said second end, characterised in that said first lumen is in communication with said second lumen near to said second end.
19. Invasive device according to claim 18 characterised in that it comprises more than 2 lumens.
20. Invasive device according to claims 18 and 19 characterised in that the hollow elongated body is opaque to radio frequency radiation.